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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,958	08/13/2001	Masayoshi Nanba	2519US0P	8993
23115	7590	06/04/2004	EXAMINER	
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC			WHITEMAN, BRIAN A	
INTELLECTUAL PROPERTY DEPARTMENT			ART UNIT	
475 HALF DAY ROAD			PAPER NUMBER	
SUITE 500			1635	
LINCOLNSHIRE, IL 60069			DATE MAILED: 06/04/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,958

Applicant(s)

NANBA ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Final Rejection

Claims 1-5 are pending examination.

Applicants' traversal, the amendment to the abstract, the amendment to the specification and the amendment to claim 1 and the cancellation of claims 6-11 filed on 4/19/04 is acknowledged and considered.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Dr. Namba's last name is incorrectly spelled in the oath.

Drawings

The drawings were received on 10/28/03. These drawings are not acceptable.

New corrected drawings are required in this application because of the objection by the draftsman. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

Claims 3 and 4 are objected to because of the following informalities: In view of the revised 37 CFR 1.121 guidelines, the status (previously amended) of claims 3 and 4 is incorrect. The status of claims 3 and 4 should be (previously presented).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 3, and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claim 1 filed on 2/5/04 introduces new subject matter into the application. The application and the originally filed claim as a whole are directed to an immortalized hepatocyte cell culture of human normal cell origin retaining an enzyme activity involved in the metabolism of xenobiotics in the liver or the capability of expressing a gene encoding an enzyme involved in the metabolism of xenobiotics in the liver.

The original specification did not disclose:

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1. An immortalized hepatocyte cell culture of human origin retaining an enzyme activity involved in the metabolism of xenobiotics in the liver or the capability of expressing a gene encoding an enzyme involved in the metabolism of xenobiotics in the liver, wherein said cell is expressing at least three endogenous cytochrome P450 CYP genes.

2. The cell culture of claim 1 wherein the enzyme activity is NADPH cytochrome P450 reductase activity, glucuronosyl transferase activity, ethoxyresorufine dealkylation activity, benzyloxyresorufine dealkylation activity, pentoxyresorufine dealkylation activity, methoxyresorufine dealkylation activity, flavin monooxygenase activity, epoxy hydratase activity, sulfotransferase activity or glutathione S-transferase activity.

3. The cell culture according to claim 1 wherein the enzyme is NADPH cytochrome P450 reductase, NADPH cytochrome P450, flavin monooxygenase, epoxy hydratase, glucurosyl transferase, sulfotransferase or glutathione S-transferase.

4. The cell culture according to claim 3, wherein the cytochrome P450 is CYP1A1, CYP1A2 or CYP3A.

There is no page cited for support of the amendment to claim 1. MPEP 714.02 states, "Applicant should also specifically point out the support for any amendments made to the disclosure. See MPEP § 2163.06." The specification teaches an immortalized hepatocyte cell culture of human normal cell origin expressing endogenous CYP1A1, CYP1A2, and CYP3A. See Figure 1 and cell culture designated FERM BP-6328. The specification contemplates an immortalized cell culture retaining one enzyme activity involved in the metabolism of xenobiotics in the liver or capable of expressing a gene encoding one enzyme involved in the metabolism of xenobiotics in the liver. See page 4. The specification provides sufficient

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description for an immortalized hepatocyte cell culture of human normal cell origin expressing endogenous CYP1A1, CYP1A2, and CYP3A. However, the specification does not describe an immortalized hepatocyte cell culture of human origin expressing a genus of endogenous P450 CYP genes, wherein at least three endogenous P450 CYP genes are expressed. In addition, the specification does not support an immortalized hepatocyte cell culture expressing at least three endogenous cytochrome P450 CYP genes and having an additional enzyme activity in claims 2-4. Thus, nothing in the specification would lead one to the particular combination set forth in the new claims. "It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997). It is apparent that the applicants at the time the invention was made did not intend or contemplate an immortalized cell culture retaining an enzyme activity involved in the metabolism of xenobiotics in the liver or the capability of expressing a gene encoding an enzyme involved in the metabolism of xenobiotics in the liver and expressing at least three endogenous cytochrome P450 CYP genes in claim 1 and an additional enzyme activity selected from claims 2-4 as part of the disclosure of their invention. There is no evidence in the specification that the applicants were possession of the claimed immortalized cell culture in the amended claim and claims dependent thereof, as it is now claimed, at the time the application was filed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the metes and bounds of the claims are not defined. The claims do not define if the phrase “wherein said cell is expressing at least three endogenous cytochrome P450 CYP genes” does or does not include “an enzyme activity involved in the metabolism of xenobiotics in the liver or the capability of expressing a gene encoding an enzyme involved in the metabolism of xenobiotics in the liver”.

Claims 2-5 are also rejected because they depend from claim 1.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

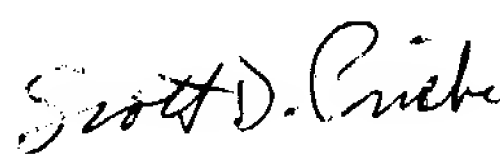
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635


SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER